



**R304**

**GENERAL REQUIREMENTS:**

**ACCREDITATION OF ISO GUIDE 34**

**REFERENCE MATERIAL PRODUCERS**

**June 2010**

© 2010 by A2LA

All rights reserved. No part of this document may be reproduced in any form or by any means without the prior written permission of A2LA.



**Part A**

**FOREWORD**

The AMERICAN ASSOCIATION FOR LABORATORY ACCREDITATION (A2LA) is a non-profit, non-governmental, public service, membership organization dedicated to operating a nationwide, broad spectrum accreditation system.

This document sets forth the general requirements for the A2LA accreditation of reference material producers. The *A2LA Accreditation Program for Reference Material Producers* is primarily designed for reference material producers who wish to demonstrate their competence by formal compliance with a set of internationally acceptable requirements for producing reference materials. The program will also provide users of reference materials with increased confidence that the reference materials being relied upon are have been produced in accordance with specified technical and management system requirements and are of appropriate quality.

The specific assessment requirements for this program are ISO Guide 34:2009, “General requirements for the competence of reference material producers” in combination with ISO/IEC 17025:2005. ISO Guide 34 sets out the general requirements in accordance with which a reference material producer has to demonstrate that it operates, if it is to be recognized as competent to carry out the production of reference materials. ISO/IEC 17025:2005 was written specifically for determining the competency of testing and calibration laboratories and is relevant when the reference material producer has its own laboratory. The reference material producer is required to meet all requirements of these two criteria documents that are relevant to its activities, before accreditation is granted.

It should also be noted that ISO Guide 34 requires compliance with ISO Guide 30:1992 (*Terms and Definitions Used in Connection with Reference Materials*), ISO Guide 31:2000 (*Contents of Certificates of Reference Materials*), and ISO Guide 35:2006 (*Certification of Reference Materials – General and Statistical Principles*.)

It is A2LA policy not to accredit or renew accreditation of a reference material producer that fails to meet the requirements listed in the relevant *Checklist*, the *Application Form*, and in this **requirements document**.

A2LA shall ensure that confidentiality is maintained by its employees and its contractors concerning all confidential information with which they become acquainted as a result of their assessments and contacts with reference material producers. Confidential information shall not be released unless authorized by expressed written permission from the reference material producers.

Peter S. Unger, A2LA President



## TABLE OF CONTENTS

	<u>Page</u>
Cover Page	1
<b>Part A - FORWARD</b>	2
Table of Contents	3
<b>Part B - CONDITIONS FOR ACCREDITATION</b>	4
<b>Part C - ACCREDITATION PROCESS</b>	4
I. Application	4
II. On-site Assessment	5
III. Deficiencies	5
IV. Corrective Action Process	6
V. Accreditation Anniversary Date	7
VI. Extensions to the Anniversary Date	7
VII. Accreditation Decisions	8
VIII. Annual Review	9
IX. Reassessment and Renewal of Accreditation	9
X. Extraordinary Assessments	10
XI. Adding to the Scope of Accreditation	10
XII. RM Producers Reference to A2LA Accredited Status	11
XIII. Adverse Accreditation Decisions	11
XIV. Suspension of Accreditation	11
XV. Withdrawal of Accreditation	12
XVI. Appeals Procedure	13
XVII. Confidentiality Policy	14
XVIII. Conflict of Interest Policy	14
<b>A2LA ACCREDITATION PROCESS DIAGRAM</b>	16
<b>A2LA APPEALS PROCESS DIAGRAM</b>	17
Document Revision History	18



## **PART B**

### **CONDITIONS FOR ACCREDITATION**

In order to attain and maintain accreditation, reference material producers must comply with the Conditions for Accreditation (A2LA R102) published by A2LA. This document is available at the A2LA website, [www.A2LA.org](http://www.A2LA.org), or from A2LA Headquarters.

In order to apply, the applicant reference material producer's Authorized Representative, must agree to the Conditions for Accreditation and must attest that all statements made on the application are correct to the best of his/her knowledge and belief. An accredited reference material producer's Authorized Representative is responsible for ensuring that all of the relevant Conditions for Accreditation are met. During the on-site assessment, the assessor will examine records and documentation to verify compliance with the Conditions for Accreditation.

## **PART C**

### **A2LA REFERENCE MATERIAL PRODUCER ACCREDITATION PROCESS**

#### I. Application

A reference material producer applies for accreditation by obtaining the application package from A2LA headquarters, then completing and submitting the appropriate application pages and **C307 - General Checklist: ISO Guide 34 Reference Material Producer Accreditation Program**, which contains the assessment requirements) and a copy of the reference material producer's quality manual. All applicants must agree to the Conditions for Accreditation (see Application), pay the appropriate fees set by the A2LA President & CEO, and provide detailed supporting information as requested in the application. This includes information on:

- Scope of reference materials produced
- Organization structure; and
- Collaborators

All documentation must be provided in English and the assessment conducted in English. An appropriate English translation of pertinent documentation must be provided as well as a translator, if needed, to facilitate the assessment.

The specific assessment requirements for this program are ISO Guide 34:2009, "General requirements for the competence of reference material producers" in combination with ISO/IEC 17025:2005. ISO Guide 34 sets out the general requirements in accordance with which a reference material producer has to demonstrate that it operates, if it is to be recognized as competent to carry out the production of reference materials. ISO/IEC 17025:2005 was written specifically for determining the competency of testing and calibration laboratories and is relevant when the reference material producer has its own laboratory. The reference material producer is required to meet all requirements of these two criteria documents that are relevant to its activities, before accreditation is granted.



**Delayed Assessment Policy:** If a reference material producer fails to undergo its full assessment within one year from receipt of the application at A2LA headquarters, the reference material producer is prompted by A2LA to take action. If no action is taken within thirty (30) days of that reminder, the reference material producer is required to begin the application process again and pay the reference material producer accreditation fees in effect at that time. Any fees paid with the initial application are refunded according to the A2LA Refund Policy.

**Refund Policy:** While the A2LA Application Fee is non-refundable, if a reference material producer withdraws the application before completion of the assessment, it may apply for a refund of up to 50 % of the A2LA annual fee(s) and the balance of the unexpended assessor deposit. There will be no refund of annual fees after the assessment has been completed. Refunds of any balance remaining on the assessor deposit will be made at the time of the accreditation decision. Any withdrawal or refund request must be in writing.

## II. On-site Assessment

Once the application information is completed and the appropriate fees are paid, A2LA headquarters staff identifies and tentatively assigns one or more assessors to conduct an on-site assessment. Assessors are selected on the basis of their technical expertise so as to be better able to provide guidance to the reference material producers. They do not represent their employers (if so affiliated) while conducting assessments for A2LA. The reference material producer has the right to ask for another assessor if it objects to the original assignment. A2LA assessors are drawn from the ranks of the recently retired, consultants, industry, academia, government agencies, and from the reference material producer and testing laboratory communities. Assessors work under contract to A2LA. Assessments may last from one to several days. More than one assessor may be required.

Assessors are given an assessor guide and checklists to follow in performing an assessment. These documents are intended to ensure that assessments are conducted as uniformly and completely as possible among the assessors and from reference material producer to reference material producer.

Before the assessment is conducted, the assessor team requests copies of quality and/or technical SOPs related to the requirements in order to prepare for the assessment. The quality manual and related documentation must be reviewed by the assessor team before the on-site assessment can begin. This review is done ideally before the assessment is scheduled. Upon review of submitted documentation, the assessor(s) may ask the reference material producer to implement corrective action to fill any documentation gaps before scheduling the assessment. A pre-assessment visit may be requested by the reference material producer as an option at this point to enhance the success of the full assessment.

Prior to scheduling the full assessment, the assessor provides an assessment agenda. The full assessment generally involves:

- An entry briefing with reference material producer's management;
- Audit of the quality system to verify that it is fully operational and that it conforms to the requirements contained in ***C307 - General Checklist: ISO Guide 34 Reference Material Producer Accreditation Program, used in combination with ISO/IEC 17025:2005;***



- Interviews with technical and administrative staff as appropriate to verify compliance;
- Examination of facilities and RM certificates of analysis;
- A written report of assessor findings; and
- An exit meeting, including the specific written identification of any deficiencies.

The objective of an assessment is to establish whether or not a reference material producer complies with the A2LA requirements for accreditation and can competently produce the categories of reference materials for which accreditation is being sought.

### III. Deficiencies

During the assessment, assessors may observe deficiencies. A deficiency is any nonconformity to the accreditation requirements such as:

- the reference material producer's inability to competently provide reference materials for which it seeks accreditation;
- the reference material producer's management system does not conform to a clause or section of ISO Guide 34 (in combination with ISO/IEC 17025), is not adequately documented, or is not completely implemented in accordance with that documentation; or
- the reference material producer does not conform to any additional requirements of A2LA such as the requirements identified in ***R102 - Conditions for Accreditation*** and this requirements document.

At the conclusion of an assessment, the assessor prepares a report of findings, identifying deficiencies which, in the assessor's judgment, the reference material producer must resolve in order to be accredited. The assessor holds an exit meeting, going over the findings and presenting the list of deficiencies (deficiency report). At a minimum, the authorized representative should attend the exit meeting, and where practical, top management, technical and quality managers should also attend. The authorized representative of the reference material producer (or designee) is asked to sign the deficiency report to attest that the deficiency report has been reviewed with the assessor. The signature does not imply that the reference material producer representative concurs that the individual item(s) constitute a deficiency. All assessment records are forwarded to A2LA for review and processing. A2LA staff has the option of requiring a follow-up on-site assessment based on the number and nature of the deficiencies cited.

Assessors may also write an 'observation' when they question the practice or competence of the reference material producer but there is not enough supporting objective evidence to justify a deficiency or the issue cannot be tied to the accreditation requirements. If this occurs, the reference material producer does not have to respond to observations in order for accreditation to be granted. However, the observations are part of the assessment record and will be followed up by the next assessor to visit the reference material producer who will check to see if that observation was addressed by the reference material producer, resulting in an improvement, or possibly may have progressed into a deficiency.



#### IV. Corrective Action Process

The reference material producer is requested to respond within one month after the date of the exit briefing detailing either its corrective action or why it does not believe that a deficiency exists. The corrective action response must include a copy of any objective evidence (e.g., procedures, records) to indicate that the corrective actions have been implemented/completed.

The reference material producer is requested to respond, in writing, within one month after the date of the exit briefing detailing either its corrective action or why it does not believe that a deficiency exists. The corrective action response must include the reference material producer's root cause analysis and a copy of any objective evidence (e.g., calibration certificates, revised procedures, paid invoices, packaging slips and/or training records) to indicate that the corrective actions have been implemented/completed. It is possible that the assessor's review of the corrective action response may be needed to determine if the response is satisfactory. If this review is expected to take more than one hour's time, A2LA may invoice the reference material producer for this time at the prevailing assessor rate. The assessor will discuss the possibility of this review with the reference material producer during the exit briefing and obtain the reference material producer's concurrence.

It is entirely possible that the reference material producer will disagree with the findings that one or more items are deficiencies. In that case, the reference material producer is requested to explain in its response why it disagrees with the assessor.

If a new applicant reference material producer fails to respond in writing within four months after the date of the exit briefing, it may be required to submit a new application and be subject to new fees and reassessment should it wish to pursue accreditation after that time.

A new applicant reference material producer that fails to respond to all its deficiencies within six months of being assessed shall be subject to being reassessed at its expense. Even if the reference material producer responds within six months, A2LA staff has the option to ask for reassessment of a reference material producer before an initial accreditation vote is taken based on the amount, extent and nature of the deficiencies.

Reference Material Producers undergoing renewal assessments must respond in writing within 30 days of the exit briefing, and resolve all deficiencies within 60 days of the exit briefing.

Failure to meet these deadlines may result in adverse accreditation action (e.g. reassessment or suspension of accreditation). The Accreditation Council panel also has the option to require reassessment of a reference material producer before an affirmative accreditation decision can be rendered.

#### V. Accreditation Anniversary Date

Accreditation is granted for a two year period. The anniversary date of a reference material producer's accreditation is established 105 to 135 days after the last day of the final on-site assessment before an initial accreditation decision, regardless of the length of time required to correct deficiencies. This date normally remains the same throughout the reference material producer's enrollment.



## VI. Extensions to the Accreditation Anniversary Date

If a reference material producer is in their renewal process and is making good faith efforts with A2LA when approaching their accreditation anniversary date, A2LA may extend their accreditation for up to an additional 90 days to complete the renewal of accreditation process. When fundamental nonconformances are identified during an assessment, extensions of accreditation are not considered until the reference material producer submits objective evidence demonstrating that the nonconformances have been addressed. Likewise, extensions are not granted when delays are due to the reference material producer's failure to respond to requests within established deadlines:

- receipt of complete renewal application after imposed due date;
- assessment not performed within assessor availability;
- receipt of response to assessor deficiency report beyond 30 days of assessment exit briefing;
- closure of all deficiencies beyond 60 days of assessment exit briefing.

When a reference material producer is granted an extension to their accreditation, a revised Certificate and Scope of Accreditation are posted to the A2LA website which reflects the extended anniversary date. Hard copies of these documents will be made available only upon request. Upon completion of the renewal process, both documents are reissued, reflecting the renewed anniversary date.

When an extension of accreditation is not considered, upon expiration, reference material producers will be removed from the A2LA Accredited list on the A2LA website and placed on a separate website list called "Organizations in the Renewal Process". Organizations on this list are currently considered *not* accredited but are somewhere in renewal process.

## VII. Accreditation Decisions

Before an accreditation decision ballot is sent to Accreditation Council members, staff shall review the deficiency responses, including objective evidence of completed corrective action, for adequacy and completeness. If staff has any doubt about the adequacy or completeness of any part of the deficiency response, the response is submitted to the assessor(s). Since all deficiencies must be resolved before accreditation can be granted, staff shall ask the reference material producer for further written response in those cases where staff recognizes that an affirmative vote is not likely because of incomplete corrective action in response to deficiencies or obvious lack of supporting evidence that corrective action has been completely implemented.

Staff selects a "Panel of Three" from the Accreditation Council members for voting. The "Panel of Three" selection takes into account as much as possible each member's technical expertise with the reference material categories for which accreditation is being sought. Especially in the case of those reference material producers seeking (re)accreditation for a wide breadth of reference material types, or for organizations seeking accreditation in multiple fields, it may be necessary to select more than three AC members in order to accomplish this. The reference material producer is consulted about any potential conflicts of interest with the Accreditation Council membership prior to sending their package to the Accreditation Council. At least two affirmative ballots (with



## *The American Association for Laboratory Accreditation*

A2LA R304 – General Requirements: Accreditation of  
ISO Guide 34 Reference Material Producers

Document Revised:  
June 16, 2010

Page 9 of 19

no unresolved negative ballots) of the three ballots distributed must be received before accreditation can be granted.

It is the primary responsibility of assessors to judge whether the observed evidence is serious enough to warrant a deficiency. However, the panel members that are asked to vote on an accreditation decision are required to make a judgment whether or not deficiencies still exist based on information contained in the ballot package. Accordingly, panel members can differ with assessor judgments, based upon their interpretation of the criteria for the specific case under question and the supporting evidence available whether a deficiency does or does not exist. Staff attempts to resolve these differences as they arise, but it remains for the panel to make the initial decision.

Staff shall notify the reference material producer asking for further written response based on the specific justification for one or more negative votes received from the panel. If further written response still does not satisfy the negative voter(s), a reassessment may be proposed or required. If a reassessment is requested by more than one voter, the reference material producer is asked to accept a reassessment. If the reference material producer refuses the proposed reassessment, a nine (9) member Accreditation Council appeals panel is balloted (see sections on XIII. Adverse Accreditation Decisions and XVI. Appeals Procedures below). If two-thirds of the appeals panel members voting agree to a reassessment, accreditation is denied until a reassessment and satisfactory reference material producer response(s) to all deficiencies are completed.


If accreditation is granted, the A2LA staff prepares and forwards a certificate and scope of accreditation to the reference material producer. The reference material producer should keep its scope of accreditation available to show clients or potential clients the specific reference material categories for which it is accredited. A2LA staff also uses the scopes of accreditation to respond to inquiries and to prepare the A2LA online directory.

### VIII. Annual Review

Accreditation is valid for two years. However, after the initial year of accreditation, the reference material producer must pay annual fees and assessor fees and undergo a one-day surveillance visit by an assessor. This surveillance visit is performed to confirm that the reference material producer's management system and technical capabilities remain in compliance with the accreditation requirements. Failure to complete the surveillance assessment within the designated time frame may result in adverse accreditation action (see Section XIII).

On an annual basis, the accredited reference material producer must pay annual fees and submit updated information on its organization, essential personnel, facilities, and reference materials produced. Objective evidence of completion of the internal audit and management review is also required.

If the reference material producer does not promptly provide complete requested documentation, or if significant changes to the facility, organization or reference materials produced have occurred, a one-day on-site surveillance visit and payment of the associated assessor fees is required.

	<i>The American Association for Laboratory Accreditation</i>	
	A2LA R304 – General Requirements: Accreditation of ISO Guide 34 Reference Material Producers	Document Revised: June 16, 2010
		Page 10 of 19

## IX. Reassessment and Renewal of Accreditation

A2LA conducts a full on-site reassessment of all accredited reference material producers at least every two years. Reassessments are also conducted when evaluations and submissions from the reference material producer or its clients indicate significant changes in the capability of the reference material producer have occurred.

Each accredited reference material producer is sent a renewal questionnaire, well in advance of the expiration date of its accreditation, to allow sufficient time to complete the renewal process. A successful on-site reassessment must be completed before accreditation is extended for another two year period.


If deficiencies are noted during the renewal assessment, the reference material producer is asked to write to A2LA within 30 days after the assessment stating the corrective action taken. All deficiencies must be resolved before accreditation is renewed for another two years (see section III).

The renewal decision process is similar to the initial decision process (see section VII. Accreditation Decisions), except as follows:

- 1) If there are no deficiencies, renewal is automatically processed without an Accreditation Council panel vote.
- 2) If there are only a few deficiencies of a minor nature (i.e., non-compliance does not directly affect the integrity of the reference material producer that is accredited) and there is sufficient objective evidence that the deficiencies have been resolved, the President may elect to renew accreditation without an Accreditation Council panel vote.
- 3) If there are major deficiencies (i.e., non-compliance directly affects the integrity of the reference material producer), the staff advises the reference material producer of the required time-frame (normally 30 days) in which to resolve all deficiencies or be subject to further actions leading to suspension or withdrawal of accreditation (see sections XIII. Adverse Accreditation Decisions, XIV. Suspension of Accreditation, and XV. Withdrawal of Accreditation). Several related minor deficiencies or repeat deficiencies from previous assessments may also be considered a major deficiency. In these cases, a ballot of the Accreditation Council panel is conducted using the same voting procedure as for initial accreditation decisions.

## X. Extraordinary Assessments

Although rare, A2LA may require reference material producers to undergo an extraordinary assessment as a result of complaints or significant changes to the reference material producer management system. Pursuant to the severity of the complaint, this ‘for cause’ assessment may be performed with little or no advance warning.

	<i>The American Association for Laboratory Accreditation</i>	
	A2LA R304 – General Requirements: Accreditation of ISO Guide 34 Reference Material Producers	Document Revised: June 16, 2010 <hr/> Page 11 of 19

#### XI. Adding to the Scope of Accreditation

A reference material producer may request an expansion to its scope of accreditation at any time. Such a request must be submitted in writing to A2LA headquarters. Each request is handled on a case-by-case basis. Unless the previous assessor can reasonably verify the competence of the reference material producer to competently produce additional categories of reference materials, based solely on documentation provided by the reference material producer and results of the previous assessment, another on-site assessment is normally required. If the assessor can recommend a scope addition without an assessment, but this recommendation requires extensive review of supporting documentation requiring more than two hour’s time, A2LA may invoice the reference material producer for this review time at the prevailing assessor rate. If the additional reference materials involve a new technology/process, another assessment is definitely required. Similarly, if a reference material producer relocates, a follow-up assessment is normally warranted.

#### XII. RM Producers Reference to A2LA Accredited Status

For rules on the use of the “A2LA Accredited” symbol, please see the document titled ***P101 - Reference to A2LA Accredited Status – A2LA Advertising Policy.***


#### XIII. Adverse Accreditation Decisions

There are various levels of status that may be assigned to reference material producers that cannot uphold the requirements for initial or continued accreditation:

**Voluntary Withdrawal** – An applicant reference material producer not yet accredited, or a renewal reference material producer, can decide to terminate further accreditation action and voluntarily withdraw from the accreditation program. The reference material producer contact must inform A2LA in writing of this request. A2LA does not publicize the fact that a new reference material producer had applied and then withdrawn.

**Inactive** – A reference material producer is designated as inactive when it has specifically requested in writing that its accreditation be allowed to temporarily expire due to unforeseen circumstances that prevent it from adhering to the A2LA Conditions for Accreditation. To regain accredited status, the Inactive reference material producer must notify A2LA in writing of this desire, agree to undergo a full reassessment, paying all renewal fees and reassessment costs. A reference material producer that has relocated is also designated as inactive until its ability to produce reference materials on its scope at the new location has been confirmed (e.g. by a visit to the reference material producer’s site).

The Inactive status can be given to a reference material producer for no longer than one year, after which time the reference material producer is removed from A2LA records and designated as withdrawn.

	<i>The American Association for Laboratory Accreditation</i>	
	A2LA R304 – General Requirements: Accreditation of ISO Guide 34 Reference Material Producers	Document Revised: June 16, 2010  Page 12 of 19

#### XIV. Suspension of Accreditation

Suspension of all or part of a reference material producer's accreditation may be a decision made by either the President and CEO or Accreditation Council panel. The accreditation applicable to a specific reference material producer may be suspended upon adequate evidence of:

- non-compliance with the requirements of a nature not requiring immediate withdrawal; (e.g. identification of significant deficiencies during an assessment);
- improper use of the accreditation symbol (e.g., misleading prints or advertisements are not solved by suitable retractions and appropriate remedial measures by the reference material producer); and
- other deviations from the requirements of the A2LA accreditation program (e.g., failure to pay the required fee or to submit annual review information within 60 calendar days after it is due, or complete a surveillance assessment within the designated time frame).


When an accredited reference material producer is suspended, A2LA shall confirm an official suspension in a certified letter, return receipt requested, (or equivalent means) to the reference material producer's authorized representative, stating:

- the cause;
- the conditions under which the suspension will be lifted;
- that the suspension will be publicized on the A2LA website;
- that the suspension is for a temporary period to be determined by the time needed to take corrective action;
- that, within thirty (30) days of receipt of the notice, the reference material producer may submit in person, or in writing, information in opposition to the suspension, including any additional information that raises a genuine dispute over material facts;
- that a further review will be conducted to consider such information and a further written notification will be sent to the reference material producer by certified mail, return receipt requested, indicating whether the suspension has been terminated, modified, left in force or converted to a withdrawal of accreditation.

#### XV. Withdrawal of Accreditation

A2LA shall withdraw accreditation for any of the following causes:

- under the relevant provisions for suspension of accreditation;
- if surveillance or reassessment indicates that deficiencies are of a serious nature as judged by the Accreditation Council panel;

	<i>The American Association for Laboratory Accreditation</i>	
	A2LA R304 – General Requirements: Accreditation of ISO Guide 34 Reference Material Producers	Document Revised: June 16, 2010
		Page 13 of 19

- when complaints are received relating to one or more of the reference material producer's certificates and investigation reveals serious deficiencies in the management system and/or competence in producing the specific reference materials;
- if the system rules are changed and the reference material producer either will not or cannot ensure conformance to the new requirements;
- on any other grounds specifically provided for under these program requirements or formally agreed between A2LA and the reference material producer;
- when such action is necessary to protect the reputation of A2LA; and
- at the formal request of the reference material producer.

When it is proposed to withdraw accreditation, A2LA shall issue a written notice by certified mail, return receipt requested:

- that withdrawal is being considered;
- of the reasons for the proposed withdrawal sufficient to put the reference material producer on notice of the cause;
- that within thirty (30) days of receipt of the notice, the reference material producer may submit in person, or in writing, information in opposition to the withdrawal, including any additional information that raises a genuine dispute over material facts; and
- of the effect of proposed withdrawal, including removing the reference material producer's name from the A2LA online directory and publicizing the action on the A2LA website.

A reference material producer may appeal to A2LA against a decision to withdraw or not to award accreditation.

#### XVI. Appeals Procedure

There are two possible levels that an appeal can reach before being resolved:

- 1) Accreditation Council; (nine member appeals panel)
- 2) Board of Directors

The A2LA staff shall advise the applicant in writing of its right to challenge an adverse accreditation decision by the President and CEO or the initial Accreditation Council panel. The appeals policy, including an applicant's right to a hearing, are contained in the A2LA Bylaws.

An appeal shall be lodged no later than thirty (30) days after notification of the decision by forwarding a certified letter to A2LA for timely consideration by the appeals panel of the Accreditation Council.



Any decision from an appeals vote which would deny or withdraw a reference material producer's complete accreditation, must be agreed upon by a two-thirds vote of those voting from the nine-member appeals panels of the Accreditation Council. Votes must be received from all members with specific technical background necessary to review the reference materials producer's scope of accreditation. The decision of the Accreditation Council's appeals group is communicated in writing to the appellant.

The decision of the Accreditation Council's appeals group is communicated in writing to the appellant.

If the decision is not favorable to the appellant, the appellant may lodge a further appeal within thirty (30) days of notification by forwarding a certified letter to A2LA for timely consideration by the Board of Directors. This letter shall include appropriate substantiation for the appeal. This letter will be promptly transmitted to the members of the Board of Directors, except to those Board of Directors members that have a conflict of interest.

The decision of the Board of Directors shall be final and is communicated in writing to the appellant.


#### XVII. Confidentiality Policy

All information provided by applicants in connection with a request for an application package, an application for accreditation, or an assessment is confidential. Such information is examined by a small group of A2LA staff, assessors, and Accreditation Council and external bodies as needed for recognition of the program. All are made aware of its confidentiality. Such information shall not be released unless the applicant provides A2LA permission in writing to do so.

Documents necessary to convey information about accredited reference material producers and their scopes of accreditation are not confidential.

In response to a question about whether or not a particular reference material producer has applied for accreditation, unless otherwise advised by the applicant, A2LA simply responds by saying that the reference material producer is not accredited. Staff should neither confirm nor deny whether a reference material producer has ever applied for accreditation. If the reference material producer itself is saying that it has applied for accreditation, it is the reference material producer's responsibility to release the information regarding its applicant status. If the caller says that the reference material producer claims it applied, staff shall take the name, address and phone number of the reference material producer to check to see if the reference material producer is misleading the client but staff still will not verify the reference material producer's application. Should the reference material producer insist that staff verify for a potential client that it has applied to A2LA, staff shall indicate that it has applied only if the reference material producer makes such a request to A2LA in writing.

If an inquiry is made about a reference material producer whose accreditation has lapsed but is in the renewal process, staff can indicate that the reference material producer is not now accredited but is in the process of renewal, if that is the case. If the renewal reference material producer's accreditation has lapsed with no indication (return of renewal forms or payment) of pursuit of renewal, staff indicates simply that the reference material producer is not accredited.

	<i>The American Association for Laboratory Accreditation</i>	
	A2LA R304 – General Requirements: Accreditation of ISO Guide 34 Reference Material Producers	Document Revised: June 16, 2010 <hr/> Page 15 of 19

If A2LA finds that a reference material producer is misrepresenting its applicant or accredited status, staff shall treat such information like a complaint by first informing the A2LA President. The President shall determine the appropriate action, which would usually involve contacting the reference material producer directly about the alleged misrepresentation.

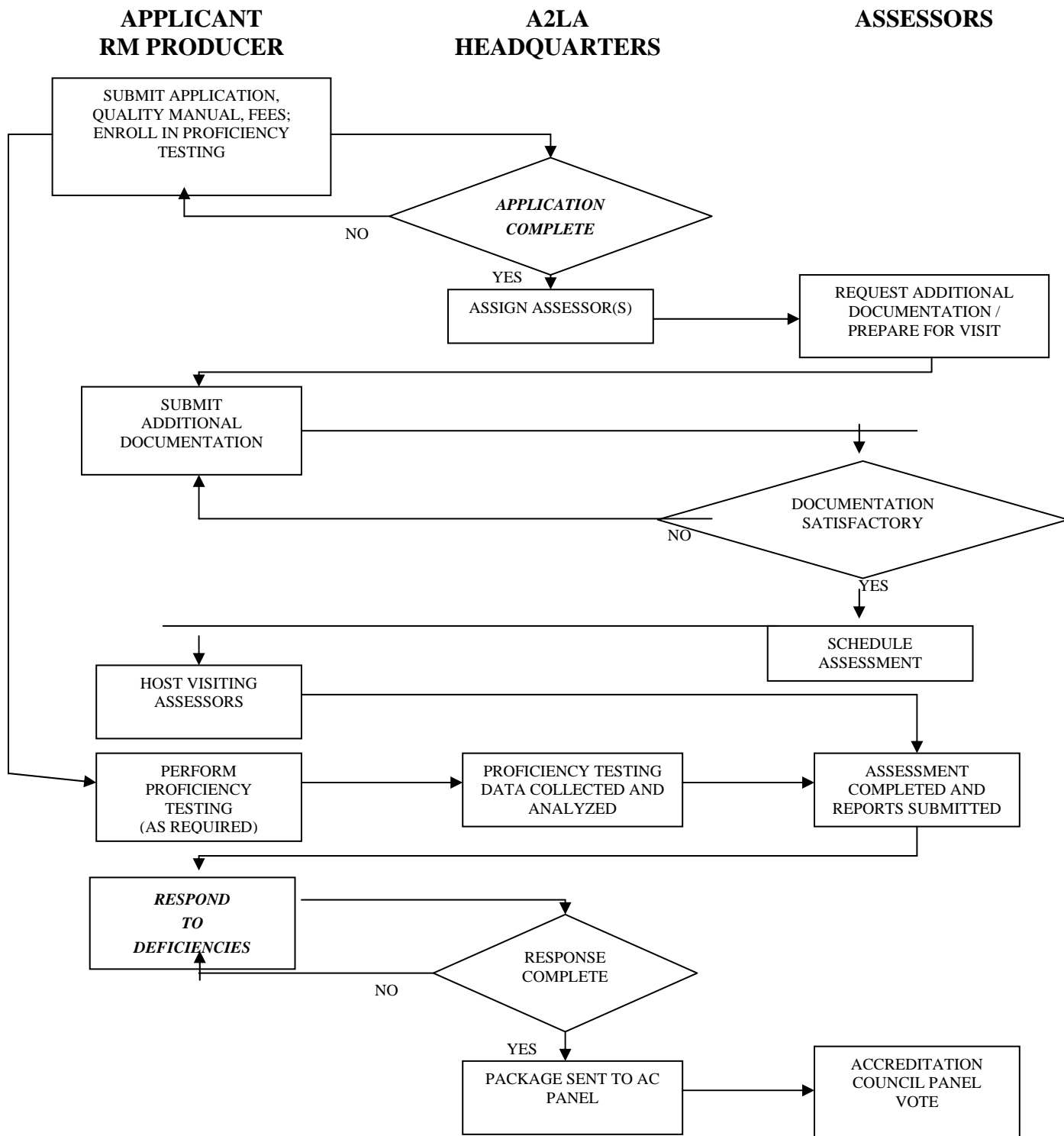
XVIII. Conflict of Interest Policy

Since its inception, A2LA has had a policy that actual or apparent conflicts of interest must be avoided as mandated by normal business ethics. A2LA believes that it is vital that its accreditation services be impartial and objective, uninfluenced by the private interests of individuals acting for A2LA. Accordingly, any person directly involved in actions relating to the A2LA accreditation process shall avoid direct participation in A2LA actions that may involve an actual or apparent conflict of interest.

The Chairman of the Board and the President shall, as promptly as possible, take all possible means to prevent or overcome any such actions that may conceivably be in violation of this policy.

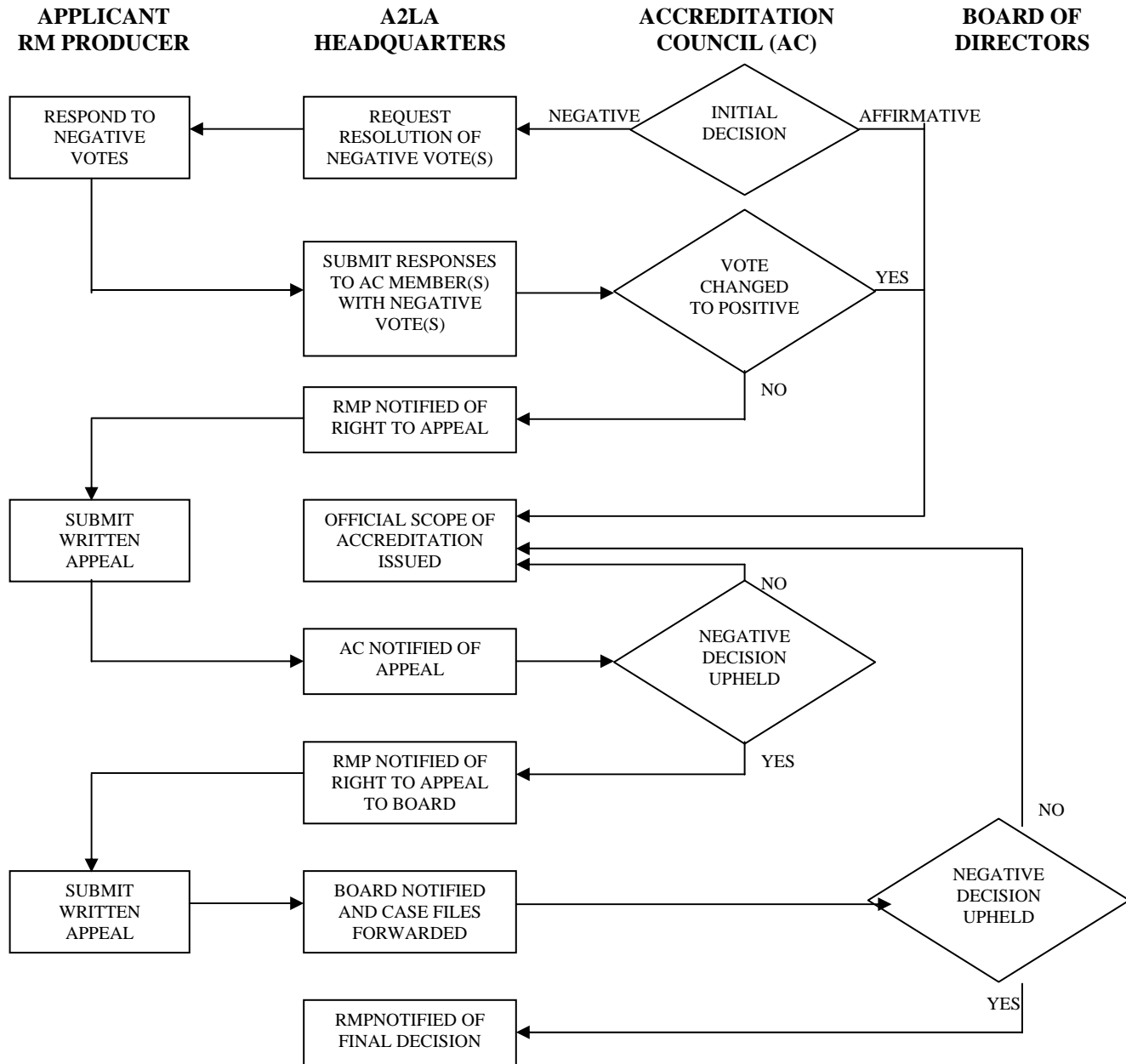


**A2LA ACCREDITATION PROCESS**





**A2LA APPEALS PROCESS DIAGRAM**





Document Revision History

Date	Description
March 2006  (Revision of January 2001 version)	Referenced updated <i>Advertising Policy</i>  Updated description of application process to include submission of quality manual  Updated ISO Standard designations  Updated timeframes for responding to deficiencies  Clarified Accreditation Council panel selection process and appeals process  Updated language in Conditions for Accreditation to be consistent with other A2LA Accreditation Programs.
May 2006 (Revision of March 2006 version)	Added the requirement for a surveillance assessment at the first year of accreditation  Added the requirement for reference material producers to submit their root cause analysis along with their objective evidence of deficiency resolution  Added a section on assessors writing ‘observations’  Broke out Corrective Action Process and Extraordinary Assessments into their own sections  Requesting an extension to the accreditation anniversary date broken out into its own section and reduced the length of extensions of accreditation to 60 days  Removed Conditions for Accreditation and including reference to Conditions  Changed name from Procedures Manual.
September 2009 (Revision of May 2006)	Added statement that President & CEO sets fee structure  Added requirement that all documents must be in English and assessments must be conducted in English  Edited reference to C307 Checklist  Clarified ISO Guide 34 in combination with ISO/IEC 17025 requirement



*The American Association for Laboratory Accreditation*

A2LA R304 – General Requirements: Accreditation of  
ISO Guide 34 Reference Material Producers

Document Revised:  
June 16, 2010

Page 19 of 19

	<p>Clarified accreditation extensions policy</p> <p>Removed A2LA Directory and newsletter references</p> <p>Clarified appeals policy</p> <p>Clarified Scope Expansion policy</p> <p>Clarified language describing various levels of accreditation</p> <p>Added flow charts showing accreditation and appeals processes</p>
<p>June 2010 (Revision of September 2009)</p>	<p>Updated ISO Guide 34:2009 Reference</p> <p>Added Delayed Assessment and Refund Policies</p>